ANNEX I TO DOD SMALLPOX RESPONSE PLAN 14 Jun 2002
MEDICAL LOGISTICS & PRODUCT DISTRIBUTION

REFERENCES.

a. United States Army Medical Command. "How To" Guide for Command Surgeons: Implementation Guidelines for Investigational New Drug (IND) Protocols. Falls Church, VA, May 2002.

b. United States Army Medical Command. "How To" Guide for Unit Leaders and Unit Health Care Providers: Implementation Guidelines for Investigational New Drug (IND) Protocols. Falls Church, VA, May 2002.

c. United States Army Medical Command. "How To" Guide for Investigational New Drug (IND) Protocols, Supplement: Smallpox Vaccination (IND # pending). Falls Church, VA, publication pending.

1. General. This annex describes instructions from the U.S. Army Medical Materiel Agency (USAMMA) for ordering, shipping, storing, controlling, accounting, and disposition of expired or suspended products. Appendix I-1 summarizes this DoD Annex on one page.

2. Mission. USAMMA will coordinate the distribution of the smallpox (vaccinia) vaccine and ancillary supplies to all medical supply activities of each of the Armed Services or other supported organizations. USAMMA will also coordinate the distribution of vaccinia immune globulin (VIG), cidofovir, and other critical medical logistic items that might be needed in implementing the DoD Smallpox Response Plan.

3. Assumptions:

a. The smallpox (vaccinia) vaccine may be either (a) licensed by the Food & Drug Administration (FDA) at the time of vaccination or (b) unlicensed but permitted by FDA to be used under Investigational New Drug (IND) provisions of the Food Drug & Cosmetic Act. If smallpox vaccine is used as an IND medication within the constructs of the DoD Smallpox Response Plan, additional education, documentation, and consent requirements apply. This iteration of Annex I assumes that smallpox vaccine is in IND status.

b. If the licensing status of these products changes during the course of the DoD response, IND products will be removed from inventory and replaced with licensed product as soon as possible.

4. Planning Factors:

a. References a, b, and c provide guidance on applicable education, documentation, and consent issues for IND medications, including smallpox vaccine and two medications to treat adverse events after smallpox vaccination (i.e., vaccinia immune globulin (VIG) and cidofovir).

b. IND products require strict procedures for logistical tracking. Medical supply activities will track these medications like controlled substances (e.g., morphine). Activities must document all product movement from the wholesale level down to patient administration.

c. Customers must ensure they have appropriate refrigeration available for storage of the vaccine or the USAMMA's Distribution Operations Center (DOC) cannot ship to the site.

5. Requisitioning.

a. USAMMA's DOC will not accept automated requisitions for smallpox (vaccinia) vaccine, VIG, or cidofovir. Vaccination sites submit requests to their supporting medical logistics activity, which will validate the requirement and submit a formal request to their strategic logistics agency (i.e., their Service Vaccine Control Center) using a DD Form 1348-6 or acceptable written alternative. A sample DD Form 1348-6 is attached as Appendix I-2.

b. Units may order VIG or cidofovir only in conjunction with IND protocols for their use, except in limited prepositioning situations. Use of VIG or cidofovir is discussed in Annexes B, G, and H.

c. The Service Vaccine Control Centers are:

(1) Navy & Marine Corps – Naval Medical Logistics Command (NAVMEDLOGCOM)

(2) Air Force – Air Force Medical Logistics Office (AFMLO)

(3) Army – U.S. Army Medical Materiel Agency (USAMMA).

(4) Coast Guard -- U.S. Army Medical Materiel Agency (USAMMA).

d. Provide the following information on the DD Form 1348-6 or alternate form:

Name of Item Requested	Smallpox vaccine (Dryvax)	Vaccinia immune globulin (VIG)	Cidofovir (Vistide)
National Stock Number (NSN)	6505-00-903-8173	6505-01-053-2600	NDC 61958-0101-01 *
Unit of Issue (UI)	VI (100-dose vial)	VI (5 ml vial)	VI (375 mg/5 ml vial)

* National Drug Code number. NSN not yet assigned.

Also enter:

(1) Document Number (including requisitioner, date, and serial number) (Army sites only),
(2) Priority – 02
(3) Quantity – quantity of units of issue required
(4) Requester's name,
(5) Requester's telephone number (commercial and DSN if available),
(6) Requester's fax number,
(7) Person who will be the shipment point of contact (POC),
(8) POC telephone number (commercial and DSN if available),
(9) POC fax number,
(10) POC e-mail (if available),
(11) Alternate POC information (identical information as requested for POC), and
(12) Shipping address (unit or facility, street address, city, state and zip code).

e. Individuals experiencing difficulties providing this information should contact the DOC at (301) 619-4121, -4128, -4411, -4318, -4198, or –4320 (DSN 343). Updated information appears at https://usamma-extranet.detrick.army.mil/cpp/index.html.

f. The Service Vaccine Control Center will provide approved requests to the DOC at fax (301) 619-4468.

g. The DOC will contact customers promptly if requests are incomplete or illegible.

6. Shipping.

a. The DOC will contact the receiving units before their scheduled shipment. During this call, the DOC and the receiving unit will discuss handling requirements. The activity will notify personnel in their receiving area and central receiving mail drop-off area. The activity will clear all gate or installation requirements for shipment delivery. For OCONUS shipments, the DOC will assist the local action officer in preparing documentation required from the Food and Drug Administration or Ministry of Health before the package arrives at Customs for clearance.

b. After calling the activity, the DOC will fax them a copy of the product receipt matrix and handling instructions. A sample of each is attached at Appendix I-3 and Appendix I-4.

c. The DOC will coordinate packaging and shipping of product(s) directly to the requesting site. In some cases, shipment escorts may be required.

d. The DOC advises the activity to track the shipment using either DHL, Federal Express, or the Defense Logistics Agency (DLA) Distribution Standard System (DSS)

Material Release Order (MRO) or Global Transportation Network (GTN) web sites or operators.

(1) DHL: www.DHL.com or 1-800-345-3579.

(2) FedEx: www.fedex.com or 1-800-463-3339.

(3) DLA DSS MRO: http://wegal.ogden.disa.mil/mrostatus/query.html.

(4) GTN: http://gtn.transcom.mil.

The DOC also tracks each shipment and provides the activity their tracking numbers upon notification of shipment.

e. Upon receipt of the product, the activity inspects the package for damage. If the package is damaged, the activity should call the DOC immediately. If shipment was completed through the DoD supply system, a report of discrepancy (ROD) should be completed for any damaged shipment. The receiving activity must complete all requirements specified on the receiving matrix faxed from the DOC earlier (Appendix I-3).

f. If the receiving activity has an urgent need to use the shipped product(s) immediately upon receipt, follow these steps:

(1) Upon receiving the shipment, the site contacts the DOC before opening the package.

(2) The DOC staff will explain procedures for conducting a check on the shipment's cold-chain maintenance status, recorded by the TempTale® temperature-monitoring device, enclosed in each shipment needing refrigeration.

(3) The receiving activity promptly removes the TempTale® from the shipping container and follow the steps exactly as described by the DOC staff (within 5 minutes of opening the shipping container).

(4) The response from the TempTale® (either Green Light or Red Light) will be relayed back to the DOC staff person, who will either provide verbal authorization to release the product for immediate use, or will tell the receiving activity that further inspection is required.

(5) The receiving activity will inspect the product and place it in an approved storage container. This is a refrigerator for smallpox vaccine and VIG (2° to 8°C, 36° to 46°F). Cidofovir is stored at controlled room temperature (25°C or 77°F), although refrigeration is acceptable.

g. If immediate release of the product is not necessary, activities should remove the product, inspect it, and store as above. If more than one container arrives, the vials from each container should be segregated and marked with the corresponding TempTale® monitor number. This provides accurate identification in case one container's monitor reads outside of required temperature parameters and is determined to be unusable. Contact the DOC to acknowledge receipt of the shipment, confirm quantity received, and confirm the express-mail air bill number for the return envelope.

h. The receiving site express-mail returns the TempTale® monitor to USAMMA's DOC, using the enclosed pre-addressed, overnight express mail envelope.

i. Upon receipt, the DOC will download the temperature data from the TempTale®. Once validated, the DOC will inform the site it may use the product, first telephonically, then with a follow-up faxed confirmation.

j. If the receiving site is located in CONUS, it returns all shipping and packaging materials using the enclosed, pre-addressed shipping label. Attach the pre-addressed shipping label to the box and send it back to the stockpile location. OCONUS locations may retain the shipping and packaging materials.

k. The DOC will not provide release of product for administration unless a proper green-light release is performed on the TempTale® monitor or the monitor is received, downloaded and approved by the USAMMA Pharmacy Consultant.

7. Storing.

a. Like most vaccines and antibody products, smallpox (vaccinia) vaccine and vaccinia immune globulin are stored in the refrigerator at 2 to 8 degrees Celsius (36–46 degrees Fahrenheit). If smallpox vaccine or VIG is exposed to temperatures above or below this level for more than 1 hour, contact the DOC at 301-619-4128, -4121, -4411, -4198, -4318, -4320 (DSN 343) for disposition instructions. Smallpox (vaccinia) vaccine and VIG can tolerate short exposures to other temperatures without degradation.

b. Cidofovir is stored at controlled room temperature (25°C or 77°F).

c. The DOC provides guidance on unusual storage conditions or distribution emergencies. Track all critical products by lot number and quantity.

8. Emergency Storage.

a. During situations when normal refrigeration systems break down, take every effort to minimize loss of product due to breaks in the cold-chain.

b. In the case of power failure or breakdown of proper storage facilities, the DOC will assist in establishing alternative emergency storage plans. The DOC has several VaxiCool® temporary-storage refrigeration units located around the world. These

VaxiCools® can be used until existing storage facilities return to proper operating order or are replaced. When a power failure or loss of storage is discovered, notify the DOC immediately. DOC personnel will assist with risk assessment, recommend actions to be taken, and assist with redistribution of product or delivery of a VaxiCool® for temporary storage. Service POCs also should be contacted shortly after the initial contact with the DOC to inform them of the situation.

9. Redistribution. Guidance for product redistribution can be obtained from the USAMMA website: https://usamma-extranet.detrick.army.mil/cpp/index.html. Contact the DOC before redistributing smallpox vaccine, VIG, or cidofovir. The effective movement of product requires constant maintenance of the appropriate storage temperature. To ensure this requirement, the product will be moved in a refrigerated container. DOC personnel must ensure maintenance of cold-chain throughout redistribution and will provide release authorization when redistribution is completed. Information on these containers can be obtained from the above-mentioned web site.

a. The DOC will provide the losing activity detailed packing instructions for the VaxiCool® or VaxiPac® container or Endurotherm Box. Gaining activities will be provided receiving and processing matrix for the transported product.

b. The DOC will send an empty container with shipping labels and a serial numbered security band to the losing activity. If the container is damaged, notify DOC immediately. If the container is in satisfactory condition, receive and process documents and pack product according to information provided.

c. With the pre-addressed, overnight express-mail label, send the VaxiCool® or VaxiPac® to the gaining unit. Call DOC to confirm overnight express-mail label account number, air bill and security band serial number for the shipment.

d. Upon receipt of the product, the gaining activity will immediately inspect the container and contents for damage and the security band for serial number accuracy. If the container or contents are damaged, notify the DOC immediately with details. If container is in satisfactory condition, receive and immediately secure product in the required refrigerated storage environment (2° to 8° Celsius or 36° to 46° Fahrenheit). Call DOC to confirm receipt and document the lot number and quantity received.

e. Process documents and product in accordance with the information provided. Call commercial carrier to schedule pickup of VaxiCool®, VaxiPac® or Endurotherm Box. Ship container back to the DOC, using the provided pre-addressed, overnight, express-mail label. Call the DOC to confirm overnight express-mail label account number and air bill serial number for the container.

f. Establish stock-record accountability of product in accordance with Service regulations.

g. Do not release the product to end-user until authorized by the DOC.

10. Control and Accountability. The lots of IND products must be handled in accordance with the control and accountability procedures of an investigational pharmaceutical.

a. Logistics activities must maintain readily retrievable records showing receipts and issues to supported activities, clinics, or other vaccination sites. This information includes the lot number and expiration date (if applicable) of the vials received or issued. Logistics sites not possessing an automated method that can readily retrieve reports of this information should implement manual procedures similar to those used for controlled substances (e.g., morphine).

b. Clinics and vaccination sites must also maintain readily retrievable records showing receipts from their supporting logistics activities, including lot number and expiration date, and local administration records showing consumption of the product they have received (i.e., number of doses administered). Vaccination sites not possessing an automated method that can readily retrieve reports on the receipt and gross usage of product should implement manual procedures as would be used for controlled substances. A sample form for a manual process is attached at Appendix I-5.

c. Clinics and vaccination sites will record individual dosage administration in Service-specific medical documentation systems, as discussed in DoD Annex B.

d. The DOC and all activities receiving IND products must provide hard-copy supply status reports to the US Army Medical Materiel Development Agency (USAMMDA) on a monthly basis. These data will include the information discussed above (receipts, issues and vaccination documentation) as well as an updated, validated inventory and will be gathered with a closing date of the last day of each month. Activities will forward/fax these data to USAMMDA for inclusion in the protocol case files not later than the seventh of each month. The USAMMDA fax number is (301) 619-2304 (DSN – 343).

11. Recovery of Unused IND Products. All unopened vials of IND medication will be accounted for and returned to USAMMA. Contact the DOC before movement of any IND medication. DOC personnel will ensure the use of appropriate packing materials and shipping containers, maintenance of cold chain, and will coordinate the movement of all smallpox vaccine to be recovered. Activities may not ship any IND medication without explicit guidance from USAMMA's DOC.

12. Disposal of Unused Non-IND Products. Activities have responsibility for disposal and destruction of unusable products other than IND products. Contact the DOC before destruction of any product issued under the DoD Smallpox Response Plan. Activities will report on-hand product inventories to be destroyed to their respective logistic agencies. The report will include information regarding lot numbers and quantities. FDA-licensed smallpox product must be handled as infectious waste. Do not discharge this item into a sanitary sewer.

a. The disposal code for FDA-licensed smallpox vaccine and FDA-licensed vaccinia immune globulin is CA01. [If used in IND status, refer to paragraph 11 above.]

b. Methods for disposal are as follows:

(1) Autoclave/Sanitary Landfill. Autoclave this item at 120 degrees Celsius for 60 minutes at 15 psi before burial in a permitted sanitary landfill.

(2) Incineration. Mix this disposal item with other combustibles and incinerate. To prevent the production of excessive air pollutants, the disposal item or combination of similar items shall not exceed 10% by weight of the total waste load charged to the incinerator at any one time.

(3) Use the following procedures if the aforementioned disposal methods are not available or immediate disposal is necessary:

(a) Contact the DOC and provide information regarding lot numbers and quantities. The DOC will provide a pre-addressed, overnight, express-mail container with packing procedures.

(b) Deface the label on each vial with red permanent marker.

(c) The activity will pack the container according to instructions provided and mail the container to DOC.

(d) The activity will call DOC to confirm overnight express-mail account number and air bill serial number for the container.

c. The disposal code for FDA-licensed cidofovir is SWA1. [If used in IND status, refer to paragraph 11 above.] Incineration if the only proper method for disposal of cidofovir. Mix this disposal item and incinerate. To prevent production of excessive air pollutants, the disposal item or combination of similar items shall not exceed 10% by weight of the total waste load charged to the incinerator at any one time.

d. Activities will prepare a certificate of disposition/destruction on DA Form 3161, Request for Issue or Turn-In, to document disposal actions and fax a copy to the DOC within 24 hours after final disposition. A sample DA Form 3161 is attached at Appendix I-6. Activities must also prepare an executive summary that documents the circumstances surrounding the wasting of the product and what actions have been taken to prevent loss of product in the future and fax to the DOC at 301-619-4468 (DSN 343).

e. Those charged with the disposal and destruction should address all questions or concerns to USAMMA Pharmacy Consultant.

13. Special Situations.

a. Ships Underway. Naval units requisition via responsible Type Commander (TYCOM) to (NAVMEDLOGCOM.

b. OCONUS Units. Procedures apply as above. For OCONUS shipments, USAMMA will assist the local action officer in preparing documentation required from the Food and Drug Administration or Ministry of Health before the package arrives at Customs for clearance. After delivery, the receiving official must complete a Customs Invoice for the TempTale® monitor to be shipped to USAMMA.

c. IND medications may not be shared or diverted without the knowledge and agreement of USAMRIID or the IND sponsor.

APPENDIX I-1
Medical Logistics & Product Distribution – Summary.

1. The U.S. Army Medical Materiel Agency (USAMMA) Distribution Operations Center (DOC) will coordinate distribution of smallpox vaccine, vaccinia immune globulin (VIG), cidofovir, and other critical medical logistic items to all medical supply activities of each of the Armed Services.

2. Coordinate with the DOC at (301) 619-4121, -4128, -4411, -4318, -4198, or –4320 (DSN 343). Updated information appears at https://usamma-extranet.detrick.army.mil/cpp/index.html. The DOC works closely with the Naval Medical Logistics Command (NAVMEDLOGCOM) and the Air Force Medical Logistics Office (AFMLO).

3. Annex I assumes that smallpox vaccine is in Investigational New Drug (IND) status. VIG and cidofovir are in IND status. Medications in IND status involve education, documentation, and consent issues addressed in greater detail in "How To" guides for command surgeons and unit health-care providers, available separately (references a, b, and c).

4. Smallpox vaccine, VIG, and cidofovir require strict logistical tracking. This annex details USAMMA instructions for ordering, shipping, storing, controlling, accounting, and disposition of expired or suspended products.

a. Ordering. Submit requests to supporting medical logistics activity, which validates requirement and submits a formal requisition (e.g., DD Form 1348-6).

b. Shipping. Requesting activities coordinate individually with USAMMA's DOC before shipment and immediately after receipt. Prevent shipments from sitting unattended at receipt, leading to product exposure to extreme temperatures and resultant wastage. For shipment overseas, plan ahead to prevent delays in customs clearance.

c. Storing. Refrigerate vaccine and VIG. Check refrigerator temperatures at least daily. Consider backup power supply. Store cidofovir at controlled room temperature.

d. Control & Accounting. Logistics activities, clinics, and vaccination sites must maintain readily retrievable records of receipts and issues. All activities must report supply status reports for IND medications monthly.

e. Disposition. Unused IND products must be returned to USAMMA. Unused non-IND products, if expired or suspended, may be disposed of according to USAMMA instructions.

APPENDIX I-2

Sample DD Form 1348-6, DoD Single Line Item Requisition System Document.

DOCUMENT IDENTIFIER			ROUTING IDENTIFIER			M & S	ITEM IDENTIFICATION* (NSN, FSCM/Part No., Other)										UNIT OF ISSUE		QUANTITY					DOCUMENT NUMBER						
							FSCM					PART NUMBER												SERV	REQUISITIONER					
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35

DOCUMENT NO. (Cont.)							DEMAND	SUPPLEMENTARY ADDRESS				SIGNAL	FUND CODE		DISTRI-BUTION CODE			PROJECT CODE			PRIORITY		REQUIRED DELIVERY DAY OF YEAR			ADVICE CODE		BLANK		
DATE			SERIAL					SERV																							
36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	
						|																											

												REJECT CODE (FOR USE BY SUPPLY SOURCE ONLY)		IDENTIFICATION DATA
														*1. MANUFACTURER'S CODE AND PART NO. *(When they exceed card columns 8 thru 22)*
70	71	72	73	74	75	76	77	78	79	80		65	66	
														2. MANUFACTURER'S NAME

3. MANUFACTURER'S CATALOG IDENTIFICATION	4. DATE *(YYMMDD)*	5. TECHNICAL ORDER NUMBER
6. TECHNICAL MANUAL NUMBER	7. NAME OF ITEM REQUESTED Vaccinia Vaccine for	
8. DESCRIPTION OF ITEM REQUESTED		8a. COLOR 8b. SIZE
9. END ITEM APPLICATION		9a. SOURCE OF SUPPLY

9b. MAKE	9c. MODEL NUMBER	9d. SERIES	9e. SERIAL NUMBER
10. REQUISITIONER *(Clear text name and address)*	11. REMARKS		

FOLD LINE FOLD LINE

DD FORM 1348-6, *Edition of Apr 77 may be used until exhausted* **DOD SINGLE LINE ITEM REQUISITION SYSTEM DOCUMENT** ***(MANUAL - LONG FORM)***

USAPPC V1.00

APPENDIX I-3
Smallpox Vaccine Receiving and Processing Matrix.

1. PURPOSE. To give detailed instructions on the receiving and processing of smallpox (vaccinia) vaccine.

2. GENERAL INFORMATION. The Secretary of Defense assigned the U.S Army as the Executive Agent for DoD's Immunization Program for Biological Warfare Defense, including protocol management for smallpox vaccination. The Surgeon General of the Army is responsible for implementation of this vaccination program.

3. SPECIFIC RESPONSIBILITIES. The local activity's chief of medical logistics designates a Receiving Official and alternate(s). The delegated Receiving Official or Authorized Alternate official is responsible for the receipt, processing, storage, security, and subsequent release to the end-user of this vaccine. This matrix details the necessary receiving and handling instructions to be followed by each Receiving Official or Authorized Alternate. This product must be handled as a critical medical materiel item requiring close control. Due to the sensitivity of this product, the Receiving Official or Authorized Alternate is personally responsible to prevent damage or spoilage caused by negligence.

STEP	CRITICAL EVENTS
1	Service Medical Logistics Agency (USAMMA, AFMLO, NAVMEDLOGCOM) contacts Receiving Official before shipment, to verify ship-to address and convey any special preliminary receipt instructions.
2	DOC calls Receiving Official or Alternate before shipment and verifies: a. Address and any other alternate receiving official(s). b. Receipt time of product (typically 1000-1200 the next day). c. Expected time of phone call (1500-1630 on day of shipment) from DOC with FedEx or DHL tracking/air bill number. d. Receiving Official has been contacted by their Medical Logistics Agency (USAMMA, AFMLO, NAVMEDLOGCOM) to confirm delivery.
3	DOC provides the Receiving Official a briefing on the details and potential risk associated with receipt of this shipment: a. All personnel in receiving area are aware of the incoming product shipment and a policy is in place to contact the Receiving Official or Authorized Alternate immediately for signature. b. Receiving Official must clear all facility (e.g., post, installation, clinic) security requirements (e.g., gate guards notified). c. Receiving Official notifies central receiving mail drop off locations of incoming product shipment from FedEx or DHL. d. Receiving Official verifies that proper refrigeration is available in the receiving area, with constant temperature monitoring capability and

STEP	CRITICAL EVENTS
	proper backup plans. e. Start tracking shipment. Call FedEx or DHL by 0800 the next day (www.DHL.com or 800-345-3579 or www.fedex.com or 800-463-3339). f. Contact DOC if delivery is not made by 1200.
4	USAMMA Distribution Operations Center (DOC) faxes Receiving Official a copy of this matrix and handling instructions a day before shipment.
5	Upon receipt of product, Receiving Official or Authorized Alternate will: a. Ask FedEx/DHL courier to wait for return shipment of TempTale® device included inside package, if possible. b. Check package for signs of damage, then open it and check for damage. If contents are damaged, notify USAMMA immediately. c. Remove handling instruction information paper, FedEx/DHL envelope (for TempTale® return to USAMMA), and FedEx/DHL label from the top of box. Note the airway bill numbers for the FedEx/DHL envelope for returning the TempTale and the FedEx/DHL label for returning the box. You will need to provide this information to the DOC in step 5(e). d. Remove top layers of gel packs, locate and remove the TempTale®, and place it in the FedEx/DHL envelope. If shipment is OCONUS, complete Customs Invoice provided for the return of the TempTale® monitor. Call FedEx or DHL for pickup. e. Call DOC to confirm receipt. If damaged, describe damage to DOC. Provide DOC with TempTale® FedEx/DHL tracking/air bill numbers for both the TempTale return envelope and the shipping box return label. f. Immediately secure product in the required refrigerated storage environment (2 to 8? Celsius, which is equivalent to 36 to 46° Fahrenheit). DO NOT FREEZE. g. Enclose all remaining packaging materials in shipping box and put FedEx/DHL label on box. Call FedEx or DHL for pickup. h. Assure stock record accountability for product is established in accordance with Service regulations. Track lot number and quantity. i. DO NOT RELEASE THE PRODUCT TO END-USER UNTIL AUTHORIZED BY THE DOC.
6	After receiving and downloading the TempTale®, the DOC will: a. Telephone the Receiving Official or Authorized Alternate with results. b. Fax Smallpox Vaccine Release Form to Receiving Official.
7	After receiving release authorization from the DOC, Receiving Official will: a. Notify pharmacy, immunization clinic, or other end user that product is available for clinical use. b. Report receipt of shipment to their Service Medical Logistics Agency.

APPENDIX I-4
Handling Instructions Of Smallpox Vaccine (Insert Into Product Shipments).

1. PURPOSE. To give detailed instructions on the receiving and processing of the smallpox (vaccinia) vaccine.

2. GENERAL INFORMATION. The Secretary of Defense assigned the U.S Army as the Executive Agent for DoD's Immunization Program for Biological Warfare Defense, including protocol management for smallpox vaccination. The Surgeon General of the Army is responsible for implementation of this vaccination program.

3. SPECIFIC RESPONSIBILITIES. This paper details the necessary receiving and handling instructions to be followed by each activity. This product must be handled as a critical medical materiel item requiring the utmost control. Accountability by lot number and quantity is required.

4. SMALLPOX (VACCINIA) VACCINE INFORMATION. The product must be refrigerated and maintained at temperatures between 2 to 8 degrees Centigrade (36 to 46 degrees Fahrenheit). DO NOT FREEZE. The refrigerator's temperature must be monitored electronically or manually and recorded on a routine basis. The National Stock Number (NSN) for this vaccine is 6505-01-399-6828.

4. SHIPPING. The carrier will be DHL or FedEx. Shipment tracking information for DHL is available at www.DHL.com or 1-800-225-5345 and for Federal Express at www.fedex.com or 1-800-463-3339. USAMMA's Distribution Operations Center (DOC) will notify each receiving activity with the shipment tracking number (air bill number).

5. RECEIPT INFORMATION. Upon receipt of the package:

a. Check package for signs of damage, then open it and check for damage. If contents are damaged, notify the DOC immediately.

b. Remove handling instruction information paper, FedEx/DHL envelope (for TempTale® return to USAMMA), and FedEx/DHL label from the top of box. Note the airway bill numbers for the FedEx/DHL envelope for returning the TempTale and the FedEx/DHL label for returning the box. You will need to provide this information to the DOC in step 5(e).

c. Remove top layers of gel packs, locate and remove the TempTale®, and place it in the FedEx/DHL envelope. If shipment is OCONUS, complete Customs Invoice provided for the return of the TempTale® monitor. Call FedEx or DHL for pickup.

d. Call DOC to confirm receipt. If damaged, describe damage to DOC. Provide DOC with TempTale® FedEx/DHL tracking/air bill numbers for both the TempTale return envelope and the shipping box return label.

e. Immediately secure product in the required refrigerated storage environment (2 to 8? Celsius, which is equivalent to 36 to 46° Fahrenheit). DO NOT FREEZE. If more than one container arrives, segregate the vials from each shipping container with the corresponding TempTale® monitor number. This provides accurate identification in case one container's monitor reads outside of required temperature parameters and is determined to be unusable.

f. Enclose all remaining packaging materials in shipping box and put FedEx/DHL label on box. Call FedEx or DHL for pickup.

g. If contents are in satisfactory condition, receive and process documents in accordance with local procedures. Assure stock record accountability for product is established in accordance with Service regulations. Track lot number and quantity.

h. DO NOT RELEASE PRODUCT TO END-USER UNTIL AUTHORIZED BY USAMMA's DOC. Release authorization will be electronically transmitted to the receiving activity once the temperature control monitors are received, downloaded and approved by USAMMA staff pharmacist.

6. SECURING SHIPMENT. DO NOT FREEZE! Products must be refrigerated at temperatures between 2 to 8 degrees Celsius (36-46 degrees Fahrenheit).

7. FINAL STEPS. After receiving release authorization from the DOC:

a. Notify pharmacy, immunization clinic, or other end user that product is available for clinical use.

b. Report receipt of shipment to your Service Medical Logistics Agency.

APPENDIX I-5
Sample Investigational Drug Accountability Record.

Investigational Drug Accountability Record for _____(product) Organization / Unit _____							
Line #	Date	Recipient / Patient's Name	Recipient / Patient's ID #	Quantity Dis-pensed or Re-ceived	Balance Forward _____ Balance	Manu-facturer & Lot #	Initials of person dis-pensing drug
X		XXXXXXXXX	XXXXXXXXX	XXXXX		XXXXXXX	XXXXXXX
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19							
20							

APPENDIX I-6

Sample DA Form 3161, Request for Issue or Turn-In.

REQUEST FOR ISSUE OR TURN-IN (DA PAM 710-2-1)		ISSUE / X TURN-IN	SHEET NO. 1	NO. SHEETS	3. REQUEST NO.		4. VOUCHER NO.	
1. SEND TO:		5. DATE MATERIAL REQUIRED			6. DODAAC	7. PRIORITY	8. ACCOUNTING/FUNDING DATA	
2. REQUEST FROM:		9. END ITEM IDENT			9a. NAME/MANUFACTURER		9b. MODEL	9c. SERIAL NO.
* CODE	ISSUE: I-Initial, R-Replacement	TURN-IN: FWT-Fair Wear And Tear, RS-Report of Survey	EX-Excess, SC-Stmt of Charges		10. PUBLICATION			11. JOB ORDER NO.

12. ITEM NO. a	STOCK NO. b	ITEM DESCRIPTION c	UNIT OF ISSUE d	QUANTITY e	CODE* f	SUPPLY ACTION g	UNIT PRICE h	TOTAL COST i	j. POSTED DATE	j. POSTED BY
		Vaccinia Vaccine								
							SHEET TOTAL		GRAND TOTAL	

13. ISSUE/TURN-IN QUANTITY COLM IS REQUESTED	DATE	BY	14. ISSUE QTY IN 'SUPPLY ACTION' COLUMN	DATE	BY	15. REC QTY IN 'SUPPLY ACTION' COLUMN	DATE	BY

DA FORM 3161, MAY 83 — REPLACES EDITION OF JUN 73 WHICH WILL BE USED UNTIL EXHAUSTED. — USAPPC V2.10